4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0510]

Clinical Development Programs for Opioid Conversion; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing a public scientific workshop to address public health concerns associated with the inclusion of equianalgesic opioid conversion tables in opioid product labels. Discussion will focus on the available data supporting the use of equianalgesic opioid conversion tables, problems associated with their use, and strategies used in clinical practice to convert patients from one opioid analgesic product to another. The goal of the workshop is to identify gaps in existing knowledge regarding equianalgesic opioid conversion in clinical practice, to develop a research agenda to address these gaps, and to identify mechanisms for communicating safe opioid analgesic conversion strategies to prescribers.

Date and Time: The public workshop will be held on July 29, 2013, from 8 a.m. to 4:30 p.m.

Location: The workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for non-FDA employees is through Building 1 where routine security check procedures will be performed. For parking and security information, please visit

http://www.fda.gov/AboutFDA/WorkingatFDA/Buildingsandfacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Persons: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3416, Elizabeth.Giaquinto@fda.hhs.gov, or Lisa Basham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1175, Lisa.Basham@fda.hhs.gov.

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: As part of the public workshop, an open public hearing will be held between 10: 15 a.m. and 11:15 a.m. on July 29, 2013. If you wish to attend the public workshop or provide testimony for the open public hearing, please email your registration to: IssuesWithOpioids@fda.hhs.gov by July 15, 2013. Those without email access may register by contacting one of the persons listed in the Contact Persons section of the document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

For those interested in providing testimony for the Open Public Hearing, please also provide a short abstract of your remarks by July 15, 2013. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony during this open public hearing may be limited by time constraints.

Registration for the public workshop is free and will be on a first-come, first-served basis. Early registration is recommended, because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If

registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: http://www.fda.gov/Drugs/NewsEvents/ucm340470.htm.

Comments: Submit either electronic or written comments by August 29, 2013. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

If you need special accommodations due to a disability, please contact Elizabeth Giaquinto or Lisa Basham (see Contact Persons) at least 7 days in advance of the public workshop.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing this workshop to address public health concerns associated with the inclusion of equianalgesic opioid conversion tables in opioid product labels. Use of these conversion tables, intended for safe conversion between opioid products, has resulted in prescribing errors, serious adverse events, and deaths. While FDA will be giving a brief presentation on the use of conversion tables in the current product labels, we are holding this scientific workshop to bring the academic experts together to achieve consensus on what does or does not need to be done to improve how opioids are converted in clinical practice.

During the public workshop participants will do the following:

1. Review the data available supporting the basis of equianalgesic opioid conversion tables.

2. Review the problems associated with the use of equianalgesic opioid conversion tables, including prescribing errors and the occurrence of serious adverse events and deaths, with emphasis on the risks associated with extended-release opioids.

3. Review clinical strategies used for converting patients from one opioid product to another opioid product and the data to support the safety of those strategies.

4. Discuss gaps in the existing knowledge regarding equianalgesic opioid analgesic doses and opioid conversion in clinical practice.

5. Develop a research agenda to address those gaps.

6. Discuss the mechanisms for communicating about safe opioid analgesic conversion strategies to prescribers.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: http://www.fda.gov/Drugs/NewsEvents/ucm340470.htm.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at http://www.regulations.gov, and may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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